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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,264	04/24/2001	Ranjani V. Parthasarathy	56286USA4A.003	5359

7590 10/15/2002

Attention: Paul W. Busse
Office of Intellectual Property Counsel
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EXAMINER	
NAFF, DAVID M	
ART UNIT	**PAPER NUMBER**
1651	4

DATE MAILED: 10/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/841,266	Parthasarathy et al
Examiner	**Group Art Unit**
[illegible]	1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

X Responsive to communication(s) filed on 7/22/02.

This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

X Claim(s) 1-45 is/are pending in the application.

Of the above claim(s) 25-45 is/are withdrawn from consideration.

Claim(s) ____ is/are allowed.

X Claim(s) 1-24 is/are rejected.

Claim(s) ____ is/are objected to.

Claim(s) ____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on ____ is approved disapproved.

The drawing(s) filed on ____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) ____.

received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: ____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). ____

X Notice of Reference(s) Cited, PTO-892

Notice of Draftsperson's Patent Drawing Review, PTO-948

Interview Summary, PTO-413

Notice of Informal Patent Application, PTO-152

Other ____

Office Action Summary

In a response of 7/22/02 to a restriction requirement of 6/17/02, applicants elected the Group I claims 1-24 without traverse.

Claims 25-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 3 filed 7/22/02.

Claims examined on the merits are 1-24.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-16, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (5,861,251) in view of Shultz et al (6,242,235 B1) and Hayes et al (5,721,123).

The claims are drawn to a composition containing an enzyme which can be a polymerase, a dye that inactivates the enzyme and a nonionic or

zwitterionic surfactant that inhibits inactivation of the enzyme by the dye. Also claimed is a method of stabilizing an enzyme by combining the surfactant with the enzyme the dye.

Park et al disclose a PCR reagent mixture containing a polymerase, a dye and a nonionic surfactant (col 3, lines 1-30). The nonionic surfactant improves reactivity of the PCR mixture.

Shultz et al disclose stabilizing polymerases with nonionic surfactants (col 6, lines 40-43).

Hayes et al disclose using heat absorptive dyes for enhancing the heating effect of electromagnetic radiation when carrying out the PCR process (col 3, lines 7-36).

It would have been obvious to include in the PCR reagent mixture of Park et al a nonionic surfactant to obtain its function to improve reactivity as taught by Park et al and to obtain its function to stabilize the polymerase as taught by Shultz et al. It would have been further obvious to include in the reagent mixture a heat absorptive dye to obtain its function of enhancing the heating effect of electromagnetic radiation as taught by Hayes et al. The dye of Park et al and/or the heat absorptive dye of Hayes et al would have inherently reduced polymerase activity in the absence of the surfactant. Selecting another surfactant such as a zwitterionic surfactant that functions to stabilize polymerase similar to a nonionic surfactant would have merely required limited routine experimentation and been obvious.

Claims 2-4, 17-19, 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1, 5-16, 20 and 23 above, and further in view of Nadeau et al (5,919,630).

The claims require the dye to be a near-IR dye.

Nadeau et al disclose using near-IR dyes as part of a donor/acceptor dye pair for carrying out the PCR (col 9, line 38, and col 2, line 42).

When modify the PCR reagent mixture of Park et al as set forth above, it would have been obvious to further include in the PCR reagent mixture a near-IR dye to obtain its function in a donor/acceptor dye pair as taught by Nadeau et al.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 09/841,272. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed composition and method would have been obvious from the claims of the copending application that require a composition containing an enzyme such as a polymerase, a nonionic or zwitterionic surfactant and a near-IR dye.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN
10/11/02

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651